

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

James D. Marks

Application No.: 09/556,945

Art Unit: 3626

Filed: April 21, 2000

Examiner: Robert W. Morgan

For: **SYSTEM AND METHOD FOR
RECRUITMENT OF CANDIDATES FOR
CLINICAL TRIALS WHILE MAINTAINING
SECURITY**

DECLARATION OF BONNIE GOLDMAN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Bonnie Goldman, hereby declare and state as follows:

1. I am a citizen of the United States and am more than twenty-one years of age.

2. From August 1995 to November 18, 1999, I was employed by Body Health Resources Corporation ("BHRC") as a consultant with the title Content Manager. Since November 19, 1999, I have been an employee of BHRC. As a consultant and an employee, I have worked on behalf of and under the direct supervision and control of James D. Marks, Founder and Chief Executive Officer.

3. The following paragraphs describe work that was completed by me, along with individuals working on my behalf and under my supervision and control. The work was completed in the United States.

4. I directed the design and implementation of web site pages on www.thebody.com presenting a Health Survey Questionnaire and accompanying information about the purpose and use of the Questionnaire (including information about the protection of privacy of the respondents and confidentiality of the responsive data). The purpose of the Health Survey Questionnaire was to solicit health and contact information from members of the public, provided with gratuitous access to the web site, for possible participation in one or more upcoming clinical trials. The Health Survey Questionnaire was first installed on a server for posting on www.thebody.com and made accessible to members of the public through access to www.thebody.com via the Internet between May 21, 1999 and, at the latest, May 24, 1999, the first date for which www.thebody.com received responses to the Questionnaire (see Exhibit C). The launch date and receipt of responses from the Health Survey Questionnaire is prior to the publication of "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet," PR Newswire, June 28, 1999 (the "drkoop.com press release").

5. I further directed the design and implementation of a secure database for BHRC in which the data entered in response to the Health Survey Questionnaire was transmitted, stored and accessed by Dahlia Elsayed, an employee of BHRC at the relevant time. The secure database resulting from the responses to the Questionnaire contained personal and medical information from multiple members of the public. In addition, I generally instructed Dahlia Elsayed to periodically download, store and print hard copies of the responses to the Health Survey Questionnaire and to store electronic and hard copy data in a secure fireproof file cabinet located at the office of BHRC in strict accordance with the privacy and confidentiality policies for the responses to the Questionnaire. More particularly, I provided the following instructions to Dahlia Elsayed for the handling of the data files:

a. DOWNLOADING: Download survey responses once a week by going to www.thebody.com/survey/health_survey/html, entering the dates for the responses to download and a predetermined user name and password (the user name and password are omitted

from this declaration in order to protect the privacy of the respondents and the confidentiality of the data). This procedure results in an encrypted e-mail transmission of responses collected from BHRC's leased server space hosted at the facilities of Interport Communications Corp., BHRC's hosting services provider, to the address research@thebody.com.

b. **RETRIEVING:** From the start menu, choose "settings," then "control panel," then click on the "mail and fax" icon. This will open a box for "Body Office Properties." Then, click on a button called "properties." Next, click on a tab called "servers" and change the login information to a predetermined account name and password (the name and account name are omitted from this declaration in order to protect the privacy of the respondents and the confidentiality of the data). The e-mail from Interport will arrive in BHRC's mailbox from the sender "postmaster" with the subject "Health Survey Responses."

c. **OPENING/DECRYPTING:** When the message is opened, it will be encrypted. To decrypt the data, click on the "Decrypt Message and Verify Signature" icon and, when prompted, enter the given passphrase for a listed key (the passphrase text is omitted from this declaration in order to protect the privacy of the respondents and the confidentiality of the data) and then click "ok."

d. **SAVING/PRINTING:** Copy the text of the e-mail from Interport into Microsoft Word, inserting page breaks between each respondent, and save the WORD file on a zip disk labeled "Reponses" with the file being saved as the date of the download.

6. As a result of the instructions provided to Dahlia Elsayed, hard copies as well as electronic copies of the Health Survey Responses were retrieved, saved and printed. Attached as Exhibits A, B and C are evidence of the Health Survey Responses received by www.thebody.com prior to June 28, 1999 and processed according to the procedures above by Dahlia Elsayed. More particularly,

a. Attached as Exhibit A is a true copy of the jacket cover from the zip disk containing the Health Survey Responses for responses for the initial responses which were received from May 24, 1999 to April 12, 2000. The jacket cover of Exhibit A was prepared by Dahlia Elsayed; she attests to its authenticity in her declaration. The jacket cover

contains the hand written description of the contents as "Health Survey Responses... launched 5/25/99."

b. Attached as Exhibit B is a true copy of the file index listing of the zip disk of Exhibit A. The file index of Exhibit B was generated by Dahlia Elsayed as part of the process of saving data to the zip disk; she attests to its authenticity in her declaration. The index includes: column 1 provides the file name which corresponds to the date the Health Survey Responses data was saved to the disk; column 2 provides the time stamp for saving the file; column 3 provides the storage amount of the data; and, column 4 provides the extended name of the file.

c. Attached as Exhibit C is a true copy of a hard copy listing of the Health Survey Reponses from May 24, 1999 to June 27, 1999, with redaction of specific data.

i. Each response contains a "Date Submitted" field which provides the date of data entry. The hard copy listing includes only a portion of the files listed on the zip disk file index (Exhibit B) because only those responses prior to June 28, 1999 are relevant.

ii. The earliest responses were submitted on May 24, 1999. There are two May 24, 2004 responses, one is a test response submitted by one of BHRC's employees via the public interface at www.thebody.com and the other is from a member of the public unaffiliated with BHRC. In addition, at least two of the responses from May 25, 2004 are from members of the public unaffiliated with BHRC. Therefore, responses to the Questionnaire by multiple members of the public were received prior to the June 28, 1999 publication date of drkoop.com press release.

iii. Each response contains a series of predetermined questions with answers provided by the respondent. Answers which could reveal confidential information of respondents has been redacted for this exhibit in order to maintain the privacy of the respondents and the confidentiality of the data. The redacted data from responses submitted prior to June 28, 1999 was personal contact and medical information from members of the public and such data was received from at least two members of the public. Therefore, the secure database

generated from responses to the Questionnaire dated May 24, 1999 and May 25, 1999 contained personal contact and medical information from at least two members of the public who provided electronic consent to volunteer for consideration as a potential candidate for existing and future clinical trials.

iii. In order to submit the data which appears in the responses of Exhibit C to www.thebody.com, each respondent had to provide electronic consent to a Participation Agreement. The Participation Agreement required that the respondent consent to volunteer for consideration as a potential candidate for existing and future clinical trials. Failure to provide electronic consent to the Participation Agreement precluded submission of the response so that no response would be generated. As a result, each response in Exhibit C corresponds to a respondent who provided electronic consent to volunteer for consideration as a potential candidate for existing and future clinical trials.

iv. The hard copy responses of Exhibit C were generated by Dahlia Elsayed; she attests to their authenticity in her declaration. The redactions of selected data contained in the responses were performed by Jason Dewey, an employee of BHRC; he attests to the purpose of the redactions and the contents of the redacted data in his declaration.

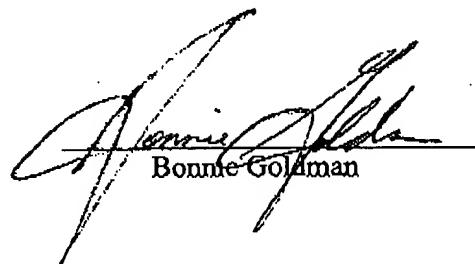
7. In addition, I directed the design and publication of a public announcement of the Health Survey Questionnaire which were available to the members of the public unaffiliated with BHRC prior to the June 28, 1999 drkoop.com press release. On May 26, 1999, I oversaw the preparation and distribution of a notice announcing the Health Survey Questionnaire to members of the public who were subscribers to the e-newsletter of www.thebody.com. Attached as Exhibit D is a true copy of the May 26, 1999 announcement. I declare that this text was transmitted via e-mail to members of the public who subscribed to the e-newsletter of www.thebody.com. I further declare that I am aware of at least one member of the public unaffiliated with BHRC, who received the e-newsletter on May 26, 1999.

8. I further declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title

18 of the United States code, and that such willful false statements may jeopardize the validity of the instant application or of any patent issued thereupon.

Dated:

August 19, 2004



A handwritten signature in black ink, appearing to read "Bonnie Goldman".

Bonnie Goldman